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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/748,783 | 12/26/2000 | David R. Goodlett | P-IS 4369 | 3333 |

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EXAMINER

MAHATAN, CHANNING

| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 12/17/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,783

Applicant(s)

GOODLETT, DAVID R.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) ☒ The proposed drawing correction filed on 16 September 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 1 Sheet 6) ☐ Other: _____

DETAILED ACTION*APPLICANTS' ARGUMENTS*

Applicants' arguments in Paper No. 13, filed 13 September 2002, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Additionally, the species election requirement set forth in Paper No. 7, mailed 14 March 2002 is vacated, thus subject matter directed to absence of ion selection, presence of ion selection, identification of a polypeptide without quantitation of said polypeptide in a sample, and identification of a polypeptide with quantitation of said polypeptide in a sample are under examination.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-47.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in

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molecular biology is high, the results of experiments in genetic engineering are unpredictable.

While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

SCOPE OF ENABLEMENT

Claims 2, 4, 5, 14-16, 24-35, and 37-46 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for physiochemical properties (i.e. molecular mass, amino acid composition, pI, and order of elution on a chromatographic medium) (instant claims 12, 23, 36, and 47; pages 16-17, lines 5-30 and 1-5, respectively), does not reasonably provide enablement for all “characteristics associated with a polypeptide”. For example, the “characteristics associated with a polypeptide” include polypeptide “function” of which the disclosure fails to provide guidance and/or steps as to the determination of a polypeptide’s function or its utilization in the claimed invention. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-10, 12, 24, 25, 27-31, 33-38, 40-42, and 44-47 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Masselson et al. (Accurate Mass Multiplexed

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Tandem Mass Spectrometry for High-Throughput Polypeptide Identification from Mixtures, Analytical Chemistry, 15 April 2000, Volume 72, Number 8, pages 1918-1924).

It should be noted that applicants define “absence of ion selection” as “instead of a single ion being selected, no selection of ions is applied but, rather, all of the ions are fragmented, leading to many peptide fragments” (page 26, lines 23-26 and page 55, lines 8-17 of the Specification).

Masselson et al. describes a mass spectrometric (FTICR) approach to identify polypeptides from mixtures using genomic databases (*C.elegans*) involving the dissociation of several species (parent) simultaneously (instant claims 1, 2, 4, 5, 12, 24, 25, 33-38, and 44-47; Abstract; page 1918, column 2, lines 23-27; and page 1919, column 1, lines 2-7). The authors perform simultaneous determination of the mass of a subset of polypeptides in the absence of ion selection and presence of ion selection, wherein no ions are selected for or one or more ions are selected for (instant claims 6 and 24; page 1919, column 2, lines 1-22; and page 1920, column 1, lines 37-47). The computer data analysis process searches (utilized known fragmentation pathways for polypeptides and mass measurements to the determined polypeptides (parent polypeptides and their fragments) in the entire *C. elegans* database (annotated polypeptide index) (Abstract and pages 1919-1920, column 2-1, lines 23-39 and 1-28, respectively). Evaluation of the multiplexed approach using *C. elegans* full genome predicted protein database and accurate masses measured for both the parent species and their fragments (instant claims 27 and 40; page 1921, column 1, lines 26-28). The mass measured for each parent species was then searched against all masses for species on this list of possible tryptic digestion products, resulting in a set of “candidates” for each parent species (page 1921, column 2, lines 17-21). The authors

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illustrate by flow chart the algorithm utilized for the polypeptide search using multiplexed MS/MS data (Figure 3). The mass accuracy for the parent species was 2 ppm and the mass accuracy for the fragment species was 2.5 ppm, and the mass accuracy was evaluated at 10 ppm accuracy for both parent and fragment (instant claims 7-10, 28-31, 37, 41, and 42; page 1923, column 1, lines 13-16 and Table 3).

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 12-21, 23-31, 33-42, and 44-47 are rejected under 35 U.S.C. § 103 as being clearly anticipated by Masselson et al.; taken in view of Gygi et al. (Quantitative analysis of complex protein mixtures using isotope-coded affinity tags, Nature Biotechnology, 17 October 1999, Volume 17, pages 994-999).

Masselson et al. teaches the utilization of mass spectrometer to identify polypeptides from mixtures using genomic databases. Masselson et al. fails to provide the elements of quantitation of the polypeptides. Gygi et al. describes an approach for the accurate quantification and concurrent sequence identification of individual proteins within complex mixtures in a single automated operation (instant claims 3, 13-21, 23, 26, and 39; Abstract; page 995, column 2, lines 1-2). The ICAT strategy (Figure 2 and page 995, column 1-2, lines 1-8 and 1-2, respectively) provides a broadly applicable solution to quantitative proteome analysis, particularly mass spectrometry (page 998, column 2, lines 43-65).

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the method of quantitating the proteins identified in a single automated operation, as taught by Gygi et al. with Masselson et al. utilization of mass spectrometer to identify polypeptides from mixtures using genomic databases. The motivation to utilize the single automated operation described by Gygi et al would increase efficiency over separate operations.

Claims 1-47 are rejected under 35 U.S.C. § 103 as being clearly anticipated by Masselson et al.; taken in view of Gygi et al. (Quantitative analysis of complex protein mixtures using isotope-coded affinity tags, Nature Biotechnology, 17 October 1999, Volume 17, pages 994-999); further in view of Easterling et al. (Routine Parts-per-Million Mass Accuracy for High-Mass Ions: Space-Charge Effects in MALDI FTICR, Analytical Chemistry, 1 February 1999, Volume 71, Number 3, pages 624-632).

Masselson et al. and Gygi et al. are deficient in applying the method of identifying polypeptides from complex mixtures by mass spectrometry using genomic databases and quantitation of said polypeptides identified in a single automated operation to a wider range of mass accuracies (i.e. 100 ppm or greater).

Easterling et al. examines the effect of ion space-charge on mass accuracy in Fourier transform ion cyclotron resonance mass spectrometry (Abstract) and applies varying mass accuracies (instant claims 11, 22, 32, and 43; page 626, column 1, lines 34-39; page 627, column 1, lines 4-34; page 630, column 2, lines 32-43; Tables 1 and 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the inventions was made to perform a wider range of mass accuracy measurements (100 ppm or

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greater), as taught by Easterling et al. with Masselson et al.; taken in view of Gygi et al. a method of identifying polypeptides from complex mixtures by mass spectrometry using genomic databases and quantitation of said polypeptides identified in a single automated operation.

OBJECTION TO DISCLOSURE

The disclosure is objected to because of the following informalities:

The disclosure contains an embedded hyperlink on page 32, line 26. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. It is suggested that "www.ncbi.nlm.nih.gov/GenBank" be replaced with "World Wide Web address: ncbi.nlm.nih.gov/Genbank". See M.P.E.P. § 608.01 and 608.01(p).

INFORMATION DISCLOSURE STATEMENT

References were lined through in the Information Disclosure Statement, Paper No. 8, filed 08 July 2002, because said references have been previously cited by the examiner in Paper No. 7, mailed 14 March 2002.

Appropriate Correction Is Required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

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1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *December 13, 2002*

Examiner Initials: *CSM*

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1800~~
Alt 1631